Remarks

By the amendments presented Claims 1, 8-9, and 28-30 have been amended to delete therefrom citation in the preamble of reference to the composition and methods for "preventing" cold and influenza viruses.

Attached hereto is a marked-up version of the changes made to the claims as a result of the current amendments. The attached page is captioned **"Version with Markings to Show Claim Changes Made"**.

Upon entry of the amendments presented, Claims 1-9 and 20-30 remain in the present continuation examination application. No additional claims fee is due.

Invention Synopsis

The present invention is directed to respiratory tract compositions, particularly nasal compositions, which provide for the prevention and treatment of cold and influenza viruses, wherein the claimed compositions comprise a combination of pyroglutamic acid and a specifically defined organic acid for the treatment of cold and influenza viruses.

It has been found that nasal compositions containing a combination of pyroglutamic acid and an organic acid having a pKa value of from about 3.0 to about 5.0 can provide a surface pH of the nasal cavity tissue to create a nasal environment that is hostile to cold and influenza-like viruses. Nasal cavities having a pH in the range of from about 3.5 to about 5.5, which is provided by the compositions of the present invention, have been found to deter viruses which can lead to respiratory tract viral infections that can result in cold and influenza like symptoms.

Formal Matters

Claims 1-9 and 20-30 have again been rejected under 35 U.S.C. (1st paragraph) for an alleged failure to provide in the specification an enabling description for recitation in the preamble of these claims reference to the "prevention" of cold and influenza viruses. Responsive to this rejection, Claims 1, 8-9, and 28-30 have been amended to delete from the preamble citation of the terms "prevention" or "preventing", thus obviating this rejection as it would apply to these amended claims. Applicants submit that this rejection is also obviated as it would apply to Claims 2-7 and 20-27, which ultimately depends from amended Claim 1.

Art Rejection

b) Rejection under 35 U.S.C. 103 over Davidson et al. in view of Szentmiklósi et al. and Gangadharan et al.

Claims 1-9 and 20-30 have again been rejected under 35 U.S.C. 103 as being unpatentably obvious over Davidson et al. (U.S. Patent 6,080,783) in view of Szentmiklósi et al. (U.S. Patent 5,244,880) and Gangadharan et al. (U.S. Patent 5,643,582). The Examiner contends that it would have been obvious to incorporate the pyroglutamic acid disclosed in Szentmiklósi et al. or Gangadharan et al. into the zinc containing nasal composition of Davidson et al., to thereby realize Applicants' invention,

notwithstanding Szentmiklósi et al.'s failure to disclose nasal formulations and Gangadharan et al.'s disclosure of 2-pyrrolidinone-5-carboxylic acid salts rather than 2-pyrrolidinone-5-carboxylic acids. Applicants respectfully traverse this rejection as it would apply to the amended claims.

Davidson et al. disclose a viscous gel which is suitable for delivering zinc or another metal to the nasal membrane. The viscous gel of Davidson et al. comprises a carrier and preferably a zinc gluconate compound wherein the zinc gluconate produces concentrations of ionic zinc for delivery into the nasal cavity. Davidson et al. further disclose that the viscous gel has a viscosity in the range of from 5,000 to 20,00 centipoise to facilitate maintenance of the gel in the nasal cavity. Davidson et al., however, fail to disclose a nasal composition comprising a combination of pyroglutamic acid and an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

Szentmiklósi et al. disclose pharmaceutical and cosmetic compositions which comprise aqueous solutions of primycin and pyroglutamic acid. In addition to primycin and pyroglutamic acid, Szentmiklósi et al. disclose that the pharmaceutical or cosmetic compositions can optionally comprise other therapeutic actives such as antibacterial (e.g., oxolinic acid) and/or anti-inflammatory agents. The compositions disclosed in the Szentmiklósi et al. reference are further described as clear, stable aqueous solutions which are formulated as topically applicable pharmaceutical compositions and disinfecting cosmetic compositions. Szentmiklósi et al., however, fail to disclose a pharmaceutical composition in the form of a nasal composition, and certainly fail to disclose a nasal composition comprising pyroglutamic acid in combination with an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

Gangadharan et al. disclose moisturizers which are suitable for rehydrating or maintaining hydration in skin and mucous membranes, and which comprise bioadhesives in combination with humectants and water complexing agents. Suitable humectants disclosed in the Gangadharan et al. reference include 2-pyrrolidinone-5-carboxylic acid salts (i.e., pyroglutamic acid salts). Gangadharan et al. further disclose that the moisturizers can also comprise other compositional ingredients that include preservatives such as benzoic acid and its salts wherein the benzoic acid compounds can also be used as acidulants, and that include pH adjusting acidulant materials to adjust the pH value of the composition between 3-5 for vaginal applications. Furthermore, Gangadharan et al. disclose that the moisturizes can be administered to different epithelial cells for dermis and mucous membrane contact including the epithelial cells of the buccal and nasal regions. Gangadharan et al., however, fail to disclose a moisturizer in the form of a nasal composition that comprises a combination of a pyroglutamic acid and an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

Applicants submit that the combined disclosures of the Davidson et al., Szentmiklósi et al., and Gangadharan et al. references, in any combination, fail to realize Applicants' invention of Claims 1-9 and 20-30, as amended. None of these applied references teach a nasal composition comprising pyroglutamic acid in combination with an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

The Examiner contends that it would have been obvious to combine the pyroglutamic acid of Szentmiklósi et al. or Gangadharan et al. with the nasal composition of Davidson et al., to thereby realize Applicants' invention. The Examiner then asserts that Szentmiklósi et al. fail to teach nasal formulations, and that Gangadharan et al. teach at col. 4, lines 45-48, the use of pyroglutamic acid or in the alternative that pyroglutamic acid salts exist in their acidic form in an aqueous solution. Applicants submit that the Examiner has instituted hindsight to combine references with a reference that by the Examiner's admission is nonanalogous to nasal formulations (i.e., Szentmiklósi et al. failure to teach nasal formulations). The Examiner has also instituted hindsight to contend that Applicants' claims directed to compositions "comprising" pyroglutamic acid is analogous to a reference whose compound of pyroglutamic acid salt may react and form pyroglutamic acid in solution. Applicants respectfully disagree with the Examiner's combination of references for a combined teaching of Applicants' claims directed to a nasal composition comprising pyroglutamic acid in combination with an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0.

Applicants submit that a nasal composition as taught by combining the Davidson et al. and Szentmiklósi et al. references may yield a nasal composition comprising a zinc compound in combination with pyroglutamic acid, but this combination of references fails to teach or suggest Applicants' nasal composition of Claims 1-9 and 20-30 which comprises pyroglutamic acid in combination with a specifically define organic acid. Davidson et al. nor Szentmiklósi et al. teach or suggest a nasal composition comprising Applicants' organic acid. Applicants further submit that a combination of the Davidson et al. and Gangadharan et al. references may result in a nasal composition comprising a zinc compound, a pyroglutamic acid salt, and an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0, but a combined disclosure of Davidson et al. and Gangadharan et al. would fail to teach or suggest Applicants' nasal composition comprising pyroglutamic acid in combination with an organic acid having a dissociation constant (pKa) value of from about 3.0 to about 5.0

Moreover, Applicants submit that there is no motivation to combine Szentmiklósi et al. with Davidson et al. to formulate a nasal composition as taught by Applicants, prima facie or otherwise. Szentmiklósi et al. fail to teach or suggest nasal compositions altogether and, therefore, provides no motivation for the skilled artisan to even look to Szentmiklósi et al. for nasal compositions comprising pyroglutamic acid and certainly not to combine Szentmiklósi et al. teachings with Davidson et al. to result in a nasal composition that is still deficient in the nasal composition taught by Applicants. Likewise, it is not prima facie obvious to combine Gangadharan et al. with Davidson et al. because Gangadharan et al. teach in passing that his compositions can be administered nasally, but the Gangadharan et al. compositions comprise pyroglutamic acid salts, not pyroglutamic acid, and, therefore, combining Gangadharan et al. with Davidson et al. would sill not result in Applicants' invention of Claims 1-9 and 20-30 which is directed to a nasal composition comprising pyroglutamic acid.

In view of the foregoing remarks, it is submitted that the applied Davidson et al., Szentmiklósi et al., and Gangadharan et al. references, in any combination, would not obviously lead the skilled artisan to a realization of Applicants' invention of Claims 1-9 and 20-30, as amended. Accordingly the rejection of

Claims 1-9 and 20-30 as being unpatentably obvious over Davidson et al. in view of Szentmiklósi et al. and Gangadharan et al. is improper, and should be withdrawn.

Conclusions

Applicants have made an earnest effort to place the application in proper form and to distinguish their claimed invention from the applied prior art. WHEREFORE, reconsideration of this application, withdrawal of the rejections under 35 U.S.C. 112 (1st paragraph) and 35 U.S.C. 103, and allowance of Claims 1-9 and 20-30 are respectfully requested.

Respectfully submitted,

Paul J. Rennie et al.

By Joan B. Cunningham

Joan B. Cunningham
Agent for Applicants
Registration No. 43,962
(513) 622-3993

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Customer No. 27752

Version with Markings to Show Changes Made

Claims 1, 8-9, and 28-30 have been amended as follows:

Claim 1. (2nd Amendment) A nasal composition for [prevention and] treatment of cold and influenza viruses comprising pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0 wherein the combination of said pyroglutamic and organic acids provides a surface pH of the nasal cavity tissue from about 3.5 to about 5.5.

Claim 8. (Amended) A method for [preventing and] treating cold and influenza viruses wherein the method comprises the step of spraying into the nasal turbinates the composition according to claim 1.

Claim 9. (Amended) A method for [preventing and] treating cold and influenza viruses wherein the method comprises the step of spraying into the nasal turbinates the composition according to claim 5.

Claim 28. (Amended) A method for [preventing and] treating cold and influenza viruses wherein the method comprises the step of spraying into the nasal turbinates the composition according to claim 20.

Claim 29. (Amended) A method for [preventing and] treating cold and influenza viruses wherein the method comprises the step of spraying into the nasal turbinates the composition according to claim 23.

Claim 30. (Amended) A method for [preventing and] treating cold and influenza viruses wherein the method comprises the step of spraying into the nasal turbinates the composition according to claim 26.